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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/066,513	01/30/2002	Judy Senior Pinsker	MAXIM.079C1	3651
20995	7590	09/28/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			YOUNG, MICAH PAUL	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			1618	

DATE MAILED: 09/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/066,513

Applicant(s)

PINSKER, JUDY SENIOR

Examiner

Micah-Paul Young

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 December 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-17 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-17 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

Acknowledgment of Papers Received: Response dated 12/01/04.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 1,3-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over the disclosures Hellstrand et al (USPN 6,071,942 hereafter '942).

4. The '942 patent is drawn to a composition comprising histamine, histamine dihydrochloride, histamine phosphate and other salts, esters and congeners (col. 19, lin. 21). The formulation is transmucosal (col. 19, lin. 5-10), and further comprises pharmaceutically active agents such as chemotherapy agents (examples), and further penetration enhancers such as dimethylsulfoxide (col. 18, lin. 31-35). The formulation enhances penetration and increases histamine circulation in the blood in order to improve transmission of chemotherapeutic agents (examples). The formulations can further encompass solvents and gelling agents (col. 17, lin. 42 – col. 18, lin. 55). The reference however does not disclose the percentages recited in the claims. However, it is the position of the examiner that such limitations do not impart patentability since they are merely an optimization of parameters that can be determined through routine experimentation by one of ordinary skill. Where the general conditions of a claim are disclosed

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in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *See In re Aller*, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955).

5. Furthermore the claims differ from the reference by reciting various concentrations of the active ingredient(s). However, the preparation of various compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. *See In re Russell*, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

6. With these things in mind it would have been obvious to one of ordinary skill in the art to follow the teachings and suggestions of the '942 patent in order to improve the effectiveness of pharmaceutically active agents such as cancer fighting drugs in the blood stream. A skilled artisan would have been motivated to follow the suggestions with an expected result of a transmucosal formulation useful in cancer treatments.

Response to Arguments

7. Applicant's arguments filed 12/01/04 have been fully considered but they are not persuasive. Applicant argues that:

- a. There is not motivation to modify the teachings of '942.
- b. There is no reasonable level of success following the teachings of '942
- c. The '942 reference does not appreciate the problem of the instant invention, and does not teach each and every element of the claims.

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8. Regarding argument a. and b., it is the position of the Examiner that the motivation to modify the teachings and suggestions of '942. The motivation to modify the teaching would be to optimize the release of the active agent and maximize the effectiveness of the formulation. These motivations are inherent in the teachings provided. The reference teaches low concentrations of histamine, though not a specific percentage, the concentration remains low comparable to the total formulation. The reference teaches a formulation further comprising solvents, gelling agents, further pharmaceutical agents and absorption enhancers identical to those of applicant. Barring a showing of an unexpected result such as a high, more sustained blood concentration resulting from the combination, it will remain the position of the Examiner that the general teachings obviate the instant claims. The claims require an active ingredient, and histamine delivered transmucosally. This is taught by the reference, though lacking a specific percentage. It remains the position of the Examiner that an artisan of ordinary skill would be able to modify the concentration taught by '942 in order to optimize the performance of the formulation. Applicant further argues that there would be no reasonable level of success, but given the level of skill in the art the Examiner respectfully disagrees. Varying concentrations are given for the histamine content of the formulation, and the determination of the optimal concentration would fall within the realm of routine experimentation. Routine experimentation, as discussed above is not held to be patentable, unless some unexpected result, results from the determinations. Again applicant is invited to provide such unexpected results.

9. Regarding argument c., applicant argues that the reference does not concern itself with the penetration enhancing properties of histamine, and therefore does not teach each and every element of the claims. In response to this argument, the Examiner reminds applicant that a

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compound and its properties are inseparable, meaning any penetration enhancing properties associated with a histamine salt would transfer to any formulation where the compound is present. Applicant argues that the problem of the reference is different, however the only problem described by applicant is that of transmucosal delivery of active agents. Col. 19, lin. 1-43 addresses the transmucosal delivery of histamine with active agents, many identical to those of applicant. It is the position of the Examiner that this problem is met by the disclosures of the reference. Applicant further includes an absorption enhancer in the formulation as well. These compounds are included in the formulation of '942 as well, but are named as penetration enhancers. It is the position of the Examiner that applicant is attempting to argue the nomenclature of a compound, however, regardless of what the compound is classified as; its properties cannot be separated from it. The formulation of applicant is nearly identical to that of the instant claims. A solvent, gelling agent, absorption enhancer, active ingredients and histamine. Burden is shifted to applicant to provide a patentable distinction between the formulation of the '942 and that of the instant claims. Until such time the claims remain obviated by the prior art.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

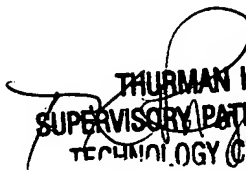
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Micah-Paul Young
Examiner
Art Unit 1618


MP Young


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
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